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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,306	04/02/1999	THOMAS GINGERAS	018547-01857	3558

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EXAMINER

SIEW, JEFFREY

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/285,306	Applicant(s) GINGERAS ET AL.	
	Examiner Jeffrey Siew	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-16 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Based on the art that was published after applicant's filing date, the prior art has disclosed a full sequence of rpoB gene of *M. tuberculosis* which was revealed to extend 3,534 base pairs(see Miller et al Antimicrob Agents chemotherapy April 1994 pp. 805-811). There is expected variation among the species of DNA which encode the mycobacterial rpoB gene. SEQ ID Nos 2 -10 are of the sizes 626 or 705bp and each sequence as being indicative of *M. avium* strain (see Table 2). The gene then would have many interspecific and intraspecific differences that would lie within and outside the claimed fragments. The specification has only disclosed only fragments that may be used to distinguish *M. avium* strain from other strains but does not provide support for all variations of the gene that lie outside the fragment. The nature of the variants is that they are variant structures where the structure and function of one does not necessarily provide guidance to the structure and function of others. The disclosure of *M. avium*

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rpoB fragments do not provide the guidance of the structure and function of the complete gene within the M. avium strain and in other strains. The common attributes of the genus, other than SEQ ID Nos 2-10, are not described. Moreover, the lower limit of 100 bases within 3533 base gene would not provide sufficient written description to the wide number of base variations of the varying species that not only lie outside 100 bases as well as the disclosed SEQ ID Nos. The specification would not provide adequate written support for such a claim. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only a few fragments of a very diverse genus is not representative of the variants of the genus and is insufficient to support the claim.

The response filed 3/3/03 has been fully considered and deemed not persuasive. The response has amended claims to recite "having". This term is still interpreted as open language. The claims are not limited solely to the SEQ ID Nos; but would still encompass a larger scope that originally raised the cited 112 first paragraph written description rejection. The response further argues that the claim language cannot be interpreted to include variations that lie outside of the fragment consisting of at least about 100 contiguous bases. The open language still allow a reasonable reading on sequence outside the 100 bases. The rejection is maintained over claim 1.

SUMMARY

2. Claims 2-10 & 11-16 are allowable. There is no prior art that teach or suggest a probe consisting of SEQ ID NO: 2-10 or a method of classifying mycobacteria by comparing the

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complete sequence of at least one sequence selected from SEQ ID NO:2-10.

Concerning claims 11-16 there is no prior art that teaches or suggests the recited polynucleotide that hybridizes under stringent hybridization conditions to SEQ ID: 2,3,4,5,6 & 9 or its complement without hybridizing to *M. tuberculosis* of SEQ ID NO:1 or its complement wherein the stringent conditions comprise 5x SSPE and 25-30°C. The closest prior art is De Beenhouwer et al who teaches fragments less than 100 base pairs complementary to SEQ ID NO:7. Claim 1 is rejected under 112 first and second paragraph and would be free of the prior art if amended to only recite "consisting of."

CONCLUSION

3. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew who can be reached at 571-272-0787. The e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (571)272-0534.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The 1600 Tech Center FAX is (703)-872-9306.



JEFFREY SIEW
PRIMARY EXAMINER

May 24, 2004